HONORABLE JUDGE THOMAS S. ZILLY

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

L.B. and M.B., on behalf of their minor child A.B., and on behalf of similarly situated others; L.B.; M.B., C.M. and A.H., on behalf of their minor child J.M., and on behalf of similarly situated others; C.M.; and A.H.,

Plaintiffs,

vs.

PREMERA BLUE CROSS,

Defendant.

Case No. 2:23-cv-00953-TSZ

DEFENDANT PREMERA BLUE CROSS' MOTION TO EXCLUDE DR. DAN KARASIC UNDER *DAUBERT*

NOTE ON MOTION CALENDAR: MARCH 14, 2025

I. INTRODUCTION

Premera Blue Cross moves to exclude Plaintiffs' expert Dr. Dan Karasic. Karasic's testimony is unreliable and does not meet the requirements of admissibility. Karasic admits the studies he relies on are low-quality and relies on studies with unvalidated metrics, insufficient sample sizes, and insufficient follow-up periods. Karasic also relies on irrelevant studies of adults (not minors) and non-surgical studies, fails to acknowledge the limited literature on gender surgery for minors, and offers unsupported assertions that cherry-pick studies to reach his conclusions. Karasic's opinions are not credible, would confuse the issues, and would not assist a trier of fact.

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II. FACTUAL BACKGROUND

1. Plaintiffs claim age and sex discrimination under Section 1557.

Premera provides broad coverage for medically necessary gender-affirming care, including puberty blockers and hormone treatments without an age limitation, and surgery for people 18 and older. Premera's Medical Policy for gender-affirming surgery provides that surgery is medically necessary when multiple mental health standards are met, including that the member has a mental health evaluation and is at least 18. These criteria are based on the scientific evidence and consistent with medical norms.

Plaintiffs allege the age limitation in Premera's Medical Policy discriminates on the basis of sex and age in violation of Section 1557 of the Affordable Care Act. But Section 1557 allows restrictions in a health plan where there are "legitimate, nondiscriminatory reason for denials or limitations of health services in benefit design and in individual cases," and "the basis for a denial or limitation" is not "unlawful animus or bias," or "a pretext for discrimination."[1] To prevail, Plaintiffs must show either: (1) Premera's Medical Policy on its face discriminates on the basis of sex and age, or (2) the Medical Policy has a disparate impact and Premera has acted with animus or bias. *Resendiz v. Exxon Mobil Corp.*, 72 F.4th 623, 630 (4th Cir. 2023). For the reasons stated in Premera's Cross-Motion for Summary Judgment [Dkt. 80], Plaintiffs cannot make that showing.

2. Dr. Karasic.

Dr. Karasic is a psychiatrist who opines that "gender-affirming chest surgeries barred from coverage by Premera's Policy are safe, effective, and medically necessary to relieve gender dysphoria for transgender people." Ex. 5 ¶138. Karasic opines that Premera's conclusion that minor surgeries are not medically necessary puts transgender individuals "at risk of significant harm to their health and wellbeing, including heightened risk of depression and suicidality." *Id.*

[1] Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37,522, 37,524 (May 6, 2024); *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 142 (2000).

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¶139. Karasic offered an opening report on named Plaintiff A.B., Ex. 5; a supplemental expert report on named Plaintiff J.M., Ex. 6; and a report that purports to rebut the opinions of Premera's expert witnesses, Ex. 7.

III. ARGUMENT

1. Standard for Admissibility.

The Court should exclude Karasic's opinion. Under Federal Rule of Evidence 702, the party offering an expert opinion bears the burden to demonstrate it is "based on sufficient facts or data," is "the product of reliable principles and methods," and is reliably applied. Fed. R. Evid. 702(b)–(d); *Daubert v. Merrell Dow Pharms.,* 509 U.S. 579, 589–90 (1993).

Evidence is unreliable if it is (1) based on "unsupported speculation and subjective beliefs"; (2) "circular, speculative, or otherwise flawed"; or (3) based on an "anemic and one-sided set of facts." *Guidroz-Brault v. Mo. Pac. R.R. Co.*, 254 F.3d 825, 829 (9th Cir. 2001). Whether evidence is reliable depends on whether it "can be (and has been) tested," whether it "has been subjected to peer review and publication," and its "general acceptance" within the relevant community. *Daubert*, 509 U.S. at 593–94; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150–51 (1999). Citation of peer-reviewed articles alone is not sufficient. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 144 (1997). Experts cannot ignore important limitations within scientific studies and must "adequately account" for "obvious alternative explanations," *Id.*; Fed. R. Evid. 702 (2000) Committee Note; *C.W. v. Textron, Inc.*, 807 F.3d 827, 837–38 (7th Cir. 2015).

2. The Court should exclude Karasic because his opinions are based on limited, low-quality evidence.

Karasic should be excluded because he admits his conclusions are based on limited, low-quality evidence. Karasic relies on the guidelines promulgated by the World Professional Organization for Transgender Health ("WPATH") known as the Standards of Care 8 ("SOC 8"). Karasic treats the SOC 8 as unassailable but does not mention the SOC 8 itself acknowledges there is no conclusive, quality evidence supporting gender surgery for adolescents: "A key challenge in adolescent transgender care is the quality of evidence evaluating the effectiveness

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of medically necessary gender-affirming medical and surgical treatments . . . the number of studies is still low, and there are few outcome studies that follow youth into adulthood." Dkt. 81-1;514–15. When shown WPATH's disclaimer, Karasic readily admitted the statement was accurate and that there is "limited data on optimal timing." Ex. 8;21:14-24:8.

Second, Karasic acknowledges reviewing but failed to assess the Hayes independent literature review, which found the evidence supporting gender surgery for minors is "minimal" and "nonexistent." Ex. 5 ¶22. The two Hayes Evolving Evidence reviews concluded the strength and quality of the evidence for gender-affirming surgeries in adolescents is (1) "minimal" based on review of full-text clinical studies, and (2) "nonexistent or unclear" based on review of systematic reviews, clinical practice guidelines, and position statements. Dkt. 80;18; Dkt. 81-2;1–26; *Id.*; 27–45.

Third, Karasic failed to address the American Society of Plastic Surgeons ("ASPS")'s position statement on the low quality of evidence for gender surgery for minors. In August 2024, the ASPS concluded "there is considerable uncertainty as to the long-term efficacy for the use of chest and genital surgical interventions for the treatment of adolescents with gender dysphoria, and the existing evidence base is viewed as low quality/low certainty," and "has not endorsed any organization's practice recommendations for the treatment of adolescents with gender dysphoria," including WPATH's. Ex. 21. ASPS leadership explained: "like Dr. Cass, we've found that the literature is of low quality and low value to dictate surgical care." Ex. 16.

Because the evidence for Karasic's opinions is of low quality, his opinions must be excluded.

3. The Court should exclude Karasic because he offered opinions that are not supported by the literature.

Karasic's opinions are inadmissible and would not assist a trier of fact because he relies on (1) studies with unvalidated metrics, unreliably-small sample sizes, and insufficient follow-up; (2) studies involving adults that do not support gender surgery for minors; and (3) non-surgical studies.

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a. Karasic relies on studies with unvalidated metrics, unreliably small sample sizes, and insufficient follow-up periods.

Karasic's opinion is unreliable because he entirely relies on low-quality studies with unvalidated metrics, unreliably-small sample sizes, and studies with only short-term follow-up that cannot accurately capture effectiveness, desistance, or regret.

First, Karasic relies on a study Dr. Olson-Kennedy authored that included an unvalidated "chest dysphoria" scale to ask participants how they felt before and after surgery. Ex. 8;107:1-16. No one in the field has sufficiently studied the relationship of a "chest dysphoria" scale to the condition of gender dysphoria it is supposed to be measuring. Ex. 23. The "chest dysphoria" scale asked subjective questions, such as "I have struggled to make future plans because of my chest," to determine participant subjective feelings. Ex. 20. Olson-Kennedy claims her chest dysphoria measure has "face validity," also known as content validity, but that just means it was in the early stages of development. Ex. 23; Ex. 12;72-76.

Second, Karasic's studies have participant sample sizes that are too small to be reliable. A study he relied on by Mehringer, for example, involved only ten participants under 18, and all of the participants were cherry-picked by the clinical team rather than randomly selected. Ex. 8;108:22-111:15.

Third, Karasic's studies have follow-up periods too short to gauge long-term outcomes:

- Olson-Kennedy's study involved an average follow-up of 1.5 years. Ex. 8;102:5-106:11. Worse, a high percentage (26%) of participants were either unreachable or refused to participate post-surgery. Ex. 20;3.
- Mehringer involved an average follow-up of 19 months. Ex. 8;108:22-111:15.
- Tang involved less than a year follow-up for a third of participants and a median follow-up of only 2.1 years. Ex. 8;123:5-124:9.

Gender surgery studies with short-term follow up periods and small sample sizes cannot adequately assess effectiveness, regret, or detransition rates, which can occur a significant time

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after surgery. There is no reliable data on detransition rates and factors associated with regret, although there is evidence that detransition rates are increasing significantly. Dkt. 83;179–80, ¶24; *Id*.; 127, ¶67.

b. Karasic relies on studies involving adult participants, irrelevant to minors.

Karasic admits there are physical and psychological differences between adolescents and adults. Ex. 8;89:18-90:22.[2] Yet Karasic nonetheless relies on studies that only involve adults. For example, Karasic relied on a study titled "Long-Term Regret and Satisfaction With Decision Following Gender-Affirming Mastectomy" to support his opinion that surgery was medically necessary for A.B. and J.M. as minors, but he later conceded that all of the participants in the study were adults. Ex. 8;150:18-151:8.

Karasic likewise relied on a study titled "Experience of Chest Dysphoria and Masculinizing Chest Surgery in Transmasculine Youth," Ex. 5 ¶68, but later acknowledged that study involved only ten participants under the age of 18 and that he should "qualify any assertions" made about a study with such a small sample size. Ex. 8;119:2-20.

Karasic also relies on studies from the Netherlands on the "Dutch approach," which was once considered the pre-eminent approach to gender affirming care, even though surgery was not available to people below 18 under the Dutch approach. Ex. 5 ¶68. Thus, studies of the Dutch approach and other adult studies do not support gender surgeries on minors.

Premera covers surgery for individuals aged 18 and older when medically necessary and covered by the terms of the individual's health plan. The narrow question at issue here is whether Premera discriminated on the basis of sex and age when it did not cover gender surgery for minors, and studies assessing surgery for adults have no bearing on this question. Karasic's opinions are unreliable because he glances past the fundamental differences between adolescents

[2] Recognizing the differences between adults and minors, the named Plaintiffs' provider Seattle Children's imposes age limits for gender surgeries. Dkt. 83;722–23. Dr. Schechter's practice at RUSH University Medical Center likewise imposes an age limit of 16 for mastectomies and 18 for genital surgeries. Ex. 4;120:20-124:6.

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and adults in order to rely on studies involving adults. *Gen. Elec.*, 522 U.S. at 144; *C.W.*, 807 F.3d at 837–38.

c. Karasic relies on non-surgical studies, irrelevant to this case.

Karasic also routinely relies on irrelevant studies assessing non-surgical treatments, such as puberty blockers and hormones. He relied on a study titled "Psychosocial Functioning in Transgender Youth After Two Years of Hormones," Ex. 5 ¶68, which (as the name suggests) did not assess any surgical participants, minors or otherwise. Karasic later admitted that the study did not examine the effectiveness of gender surgery in minors. Ex. 8;121:16-122:1.

Karasic claims that the available studies on gender care for minors are "consistent with decades of clinical experience" showing improvements in quality of life and mental health. Ex. 5 ¶68. He later acknowledged, however, that one of the studies he cites "focused on hormone therapy and puberty blockers" and only involved fifteen participants who underwent chest surgery. Ex. 8;118:9-119:24.

4. The Court should exclude Karasic because his methodology is unreliable and would not assist a trier of fact.

Karasic's opinion is unreliable because he engaged in a results-driven methodology. His opinions are biased because he selectively relies only on literature that supports his position and ignores literature that does not.

This one-sided approach fails under *Daubert* and Rule 702. Courts routinely exclude experts who selectively "cherry-picked the facts" considered to render their opinions. *Barber v. United Airlines, Inc.,* 17 F. App'x 433, 437 (7th Cir. 2001). Karasic falls victim to this "by first identifying his conclusion . . . and then cherry-picking observational studies that support his conclusion and rejecting or ignoring the great weight of the evidence that contradicts" that conclusion. *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007). Experts who present only a one-sided view of the literature give the Court a "strong reason to conclude that the witness utilized an unreliable methodology." *Fail-Safe, L.L.C. v. A.O. Smith Corp.*, 744 F. Supp. 2d 870, 889 (E.D. Wis. 2010).

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a. Karasic selectively relies on WPATH while acknowledging WPATH's bias and lack of scientific support.

Karasic selectively relies on the WPATH SOC 8 and ignores any authority to the contrary. SOC 8 initially included a minimum age for gender surgeries. But WPATH removed the age minimums after the Assistant Secretary of the Department of Health and Human Services instructed WPATH to remove them for political reasons. Dkt. 81-1;729. Karasic claimed no knowledge of the basis for their removal. Ex. 8;54:9-56:22.[3]

Most European national health systems, including the U.K., Finland, Germany and Sweden, do not allow gender surgeries on minors. Dkt. 83;19, ¶47. Despite increasing rejection of the WPATH guidelines in parts of Europe and the U.S.,[4] Karasic claims SOC8 is the unassailable standard in the medical community.

b. Karasic ignored all medical literature that does not support his conclusions.

Karasic selectively relied upon medical literature to support his conclusions. He failed to adequately consider other credible resources demonstrating the low quality of evidence and lack of longitudinal data on gender surgeries for minors, including the Cass Review, the ASPS position statement, the Hayes evidence reviews, and the McMaster systematic evidence review.

If the "relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Yates v. Ford Motor Co.*, 113 F. Supp. 3d 841, 858 (E.D.N.C. 2015). Karasic does not have to "review every single study in the relevant body of literature," but "[w]here an expert ignores evidence that is highly relevant to [her] conclusion, contrary to [her] own stated

[3] WPATH hired Johns Hopkins to conduct systematic reviews of the evidence for gender care, but after Johns Hopkins concluded there was "little to no evidence" supporting medical interventions in adolescents, Dkt. 83;830, WPATH refused to allow Johns Hopkins to publish the results because they might put WPATH in "an untenable position in terms of affecting policy or winning lawsuits." Dkt. 81-1;734–36.

[4] The permissibility of state restrictions on gender care for minors will be decided this term by the U.S. Supreme Court. *L.W. v. Skrmetti*, 83 F.4th 460, 489 (6th Cir.), *cert. granted*, 144 S. Ct. 2679 (2024).

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methodology, exclusion of the expert's testimony is warranted." *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Parks. & Prod. Litig.*, 509 F. Supp. 3d 116, 194 (D.N.J. 2020).

Karasic ignores the seminal Cass Review in his opening and supplemental report. In April 2024, the Cass Commission, commissioned by the U.K.'s National Health Service (NHS), released a final report on gender care for youth. Over a four-year period, Dr. Cass, a former Chair of the Royal Academy of Pediatrics, conducted unprecedented investigations and reviews with scholars; evaluated the existing evidence from the United Kingdom, Europe, the Americas, and elsewhere; and incorporated multiple systematic evidence reviews for gender care for minors. Dkt. 81-2;46–434; Dkt. 83;284-85, ¶¶39-40.

The Cass Review found the evidence base was low quality and that only the guidelines promulgated by Finland and Sweden – two countries that do not provide gender surgery for minors outside of the research context – had an adequate evidence base. Dkt. 83;81–82, ¶¶43-46. The NHS likewise limits gender surgeries to those aged 18 and older, and the Cass Review did not recommend any changes to that policy. *Id.*; 285, ¶41.

The Cass Review had a profound impact on the field of gender care for minors, but Karasic failed to reference the Cass Review in his opening or supplemental reports. Exs. 5-6. He later agreed that there were "certain aspects" of the Cass Review that "may have some applicability, including systematic reviews." Ex. 8;91:25-94:5. In rebuttal, he attempted to distinguish the Cass Review because it was "European" and focused on hormones and puberty blockers and because he disagreed with the Cass Commission's methods. But he simultaneously acknowledged that the experience of gender care providers globally is relevant to the provision of gender care in the U.S. Ex. 8;92:15-94:5.

Karasic also failed to address the ASPS's August 2024 position statement, which concluded: (1) "there is considerable uncertainty as to the long-term efficacy for the use of chest and genital surgical interventions for the treatment of adolescents with gender dysphoria," and

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(2) "the existing evidence base is viewed as low quality/low certainty." Ex. 21.

Karasic additionally failed to mention in his supplemental report the systematic review that was conducted through McMaster University, which is the home of a well-regarded program for evidence-based medicine, and accepted for publication in the official ASPS journal. The systematic review examined the evidence supporting mastectomies for gender dysphoria under age 26 and concluded there was "high certainty evidence for the outcomes of death, necrosis, and excessive scarring" from mastectomies and low certainty evidence about the impacts of the surgery on "quality of life, depression, gender dysphoria, postsurgical persistent pain, and body satisfaction." Dkt. 81-3;5, 13.

And Karasic failed to address the Hayes Evidence Reviews, which concluded that the strength and quality of the evidence for gender-affirming surgeries in adolescents is (1) "minimal" based on review of full-text clinical studies, and (2) "nonexistent or unclear" based on review of systematic reviews, clinical practice guidelines, and position statements. Dkt. 80;18; Dkt. 81-2;1–26; *Id*.; 27–45.

Karasic's reports give the impression that there is no evidence to the contrary. Karasic engaged in a "biased reliance on favorable sources" while ignoring position statements by leading specialty organizations and systematic reviews of the evidence that "could not be more relevant" to his opinions. *Daniels-Feasel v. Forest Pharms., Inc.*, 2021 WL 4037820, at *12 (S.D.N.Y. Sept. 3, 2021), *aff'd*, 2023 WL 4837521 (2d Cir. July 28, 2023).

5. Karasic's medical necessity opinions on A.B. and J.M. are unreliable because he failed to adequately consider their pre-existing conditions and surgical ambivalence.

Just as Karasic selectively relied on literature to support pre-determined conclusions, he selectively relied on Plaintiffs' medical records. Karasic failed to adequately consider Plaintiffs' pre-existing medical and mental health conditions and failed to take into consideration J.M.'s ambivalence.

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a. Karasic failed to adequately consider A.B. and J.M.'s preexisting medical and mental health conditions.

A.B. suffered from significant pre-existing medical and mental health conditions prior to and at the time of surgery. J.M. likewise had pre-existing mental health diagnoses prior to surgery. Karasic, however, makes little mention of these pre-existing conditions in his reports and fails to adequately assess the impact of their mental health conditions and their impact on surgery.

[redacted] Dkt. 83;309–12. [redacted] *Id.*;316–18, 341–47, 356 [redacted]; *Id.*;361 [redacted] *Id.*;379, 393. [redacted] *Id.*;319–20. [redacted] *Id.*;383–87.

[redacted] Dkt. 83;350–51. [redacted] *Id.*; 399, 404-05. [redacted] *Id.*; 424. Karasic fails to substantively grapple with A.B.'s pre-existing conditions and risks in his opening or rebuttal reports on A.B. Exs. 5, 7.

[redacted] Dkt. 83;530, 540. [redacted] *Id.*;536-37. Karasic devotes little time to these significant diagnoses and should have sufficiently taken these conditions into consideration when offering his opinions. His failure to do so renders his opinions unreliable.

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b. Karasic failed to sufficiently consider J.M.'s ambivalence towards gender care and surgery.

Karasic also ignored the repeated evidence in J.M.'s records of his ambivalence towards gender care and surgery. [redacted] Dkt. 83;546–47. [redacted] *Id.*;550. [redacted] *Id.*;554. [redacted] *Id.*;533–35. [redacted] *Id.*;559. [redacted] *Id.*;663. [redacted] *Id.*;671 [redacted] *Id.*;692 [redacted] *Id.*;694. [redacted] *Id.* J.M. ended up waiting to have surgery until the end of 2024, after his eighteenth birthday. Ex. 22. This evidence undercuts Karasic's claims that surgery was medically necessary for J.M. as a minor.

6. Karasic's opinions must be limited to rebuttal testimony.

Plaintiffs seek to certify a class based on the premise that Premera facially discriminated based on sex and age. Plaintiffs claim that expert testimony on medical necessity is irrelevant because Premera's Medical Policy constitutes a categorical exclusion. Dkt. 44;19, n.10. Plaintiffs repeatedly claim the Court need not "make individual determinations, based on expert

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testimony, as to the medical necessity" of the claims in order to decide they win. Dkt. 55;3. And Plaintiffs cite no evidence in their summary judgment motion – expert or otherwise – that gender-affirming surgery was medically necessary for A.B. or J.M.

Because Plaintiffs insist experts have no bearing on their facial discrimination claim and have represented to this Court that they are not relying on those opinions in their dispositive motions, these opinions must be offered for rebuttal purposes only and may not be offered in support of Plaintiffs' affirmative facial claim. Rebuttal testimony must be used "solely to contradict or rebut evidence on the same subject matter identified by another party" and "cannot be used to advance new arguments or new evidence." Fed. R. Civ. P. 26(a)(2)(D)(ii); *Wadler v. Bio-Rad Labs.,* No. 15-CV-02356-JCS, 2016 WL 6070530, at *3 (N.D. Cal. Oct. 17, 2016). The "proper function" of rebuttal evidence is to "contradict, impeach or defuse the impact of the evidence offered by an adverse party." *Matthew Enter., Inc. v. Chrysler Grp.* No.13-CV-04236-BLF, 2016 WL 4272430, at *1 (N.D. Cal. Aug. 15, 2016).

Karasic may only counter and attempt to distinguish the ample scientific literature cited by Premera's experts demonstrating why surgery was not medically necessary under 18 for A.B. and J.M., or for the class as a whole.

IV. CONCLUSION

The Court should exclude the opinions of Dr. Dan Karasic in their entirety. In the alternative, the Court should exclude any non-rebuttal testimony that Dr. Karasic seeks to introduce.

DATED this 29th day of January, 2025.

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I certify that the foregoing contains 4,017 words, in compliance with the Local Civil Rules.

CERTIFICATE OF SERVICE

I certify that on the date indicated below I caused a copy of the foregoing document, DEFENDANT PREMERA BLUE CROSS' MOTION TO EXCLUDE DR. DAN KARASIC UNDER DAUBERT to be filed with the Clerk of the Court via the CM/ECF system. In accordance with their ECF registration agreement and the Court's rules, the Clerk of the Court will send e-mail notification of such filing to the following attorneys of record:

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